

**In The
United States Court of Appeals
For The Federal Circuit**

**EMD MILLIPORE CORPORATION, FKA Millipore Corporation,
MERCK CHEMICALS AND LIFE SCIENCE AB, FKA Millipore AB,
and MILLIPORE SAS,**

Plaintiffs – Appellants,

v.

ALLPURE TECHNOLOGIES, INC., NKA AllPure Technologies LLC

Defendant – Appellee.

**APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
IN CASE NO. 1:11-CV-10221, JUDGE DOUGLAS P. WOODLOCK.**

**PLAINTIFFS-APPELLANTS' COMBINED PETITION
FOR PANEL REHEARING AND REHEARING EN BANC**

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Dated: October 29, 2014

CERTIFICATE OF INTEREST

Counsel for the Plaintiffs-Appellants, EMD Millipore Corporation, Merck Chemicals and Life Science AB, and Millipore SAS, certifies the following:

1. The full names of all parties represented by me are EMD Millipore Corporation, Merck Chemicals and Life Science AB, and Millipore SAS;
2. The names of the real parties in interest represented by me are EMD Millipore Corporation, Merck Chemicals and Life Science AB, and Millipore SAS;
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are identified as follows:

The plaintiff EMD Millipore Corporation identifies EMD Holding Corporation as its parent corporation and states that no publicly held company directly owns more than 10% of the stock of EMD Millipore Corporation. EMD Millipore Corporation further states that Merck KGaA, a German publicly traded company, indirectly owns 100% of EMD Millipore Corporation.

The plaintiff Merck Chemicals and Life Science AB identifies Merck Chemicals BV as its parent corporation. Through an intervening company that is not publicly traded, Merck Chemicals BV is indirectly owned by the plaintiff EMD Millipore Corporation and by Merck KGaA. For information about EMD Millipore Corporation and Merck KGaA, please see the preceding paragraph.

The plaintiff Millipore SAS identifies Merck SA as its parent corporation. 99.824% of Merck SA is owned by Merck Chemicals BV. Through an intervening company that is not publicly traded, Merck Chemicals BV is indirectly owned by the plaintiff EMD Millipore Corporation and by Merck KGaA.

Please see the initial paragraph for information about EMD Millipore Corporation; and

4. The names of all law firms whose partners or associates have appeared for the parties now represented by me are identified as follows:

Partners or associates at Hamilton, Brook, Smith & Reynolds, P.C. have appeared for the parties now represented by me. The names of all partners or associates who have appeared for the party now represented by me in the proceedings are Susan G. L. Glovsky, John L. DuPré, Lawrence P. Cogswell III, Ph.D., and Benjamin J. Sparrow.

Dated: October 29, 2014

/s/ Susan G. L. Glovsky
Susan G. L. Glovsky

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RULE

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**STATEMENT OF COUNSEL UNDER
FEDERAL CIRCUIT RULE 35(b)**

Based on my professional judgment, I believe the Panel decision is contrary to the following decisions of the Supreme Court of the United States or the precedents of this Court: *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1996); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc); *Honeywell Int’l v. Hamilton Sundstrand Corp.*, 370 F.3d 1131 (Fed. Cir. 2004) (en banc); *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097 (Fed. Cir. 2002) (precedential); *Ericsson v. Harris*, 352 F.3d 1369 (Fed. Cir. 2003) (precedential).

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

Whether the Federal Circuit is going to depart from longstanding precedent that amendment-based estoppel is determined with reference to amendment of the ***limitation at issue***

Assuming the Federal Circuit decides, contrary to longstanding precedent, that a narrowing amendment to a limitation (here “seal”) can trigger a *Festo* presumption (“infectious *Festo* presumption”) with respect to a different limitation that was not narrowed (here “removable, replaceable transfer member”):

Whether such an infectious *Festo* presumption only leads to estoppel as to recapture of equivalents that lie within the surrendered ground ***between the original claim limitation and the amended claim limitation***

Whether such an infectious *Festo* presumption is ***rebutted*** where (as found by the district court) the reasons for the narrowing amendment to the seal limitation bear no more than a tangential relationship to the equivalent in question

Dated: October 29, 2014

/s/ Susan G. L. Glovsky
Susan G. L. Glovsky
Hamilton, Brook, Smith & Reynolds, P.C.
Attorney of Record for Plaintiffs-Appellants

**POINTS OF LAW OR FACT OVERLOOKED
OR MISAPPREHENDED BY THE PANEL OF THE COURT**

In addition to departing from identified precedents, the Panel overlooked or misapprehended the following issues of law or fact:

Even if narrowing one limitation could in turn trigger a *Festo* presumption as to another limitation, the Panel finding (contrary to the finding of the district court) that Millipore had failed to rebut the presumption is based on errors of law and fact

The Panel decision affirming a finding of no literal infringement with respect to the “removable, replaceable transfer member” limitation is based on a material error of fact resulting from a misstatement of counsel’s colloquy with the district court

ARGUMENT

I. INTRODUCTION

This Petition urges the Panel and the en banc Court to adhere to precedent requiring that prosecution history estoppel be a limitation by limitation inquiry. The Panel in this case erred in failing to maintain the rigor of the estoppel inquiry required by Supreme Court and Federal Circuit precedents by finding that a narrowing of one limitation worked an estoppel with respect to another limitation.

This error should be corrected by the Panel on rehearing or, if necessary, by this Court sitting en banc. Once corrected, this Court can reach Millipore's appeal of the district court's finding of no infringement under the doctrine of equivalents left unconsidered by the Panel.

II. BACKGROUND

A. Limitations of asserted Claim 1

Briefly, Claim 1 of the '543 Patent is directed to "[a] device ... comprising: **at least one removable, replaceable transfer member ... said transfer member comprising ... a seal for sealing said aperture ... wherein the seal has a first end comprised of a bellows-shaped part sealingly attached to said holder, and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part**" A53 (emphasis added).

The two limitations in bold type above are hereinafter referred to as the "removable, replaceable transfer member" limitation and the "seal" limitation. Millipore has argued that amendment of originally presented language in Claim 1, "the transfer member (1) is removable for replacement thereof after use" A341, *broadened* the limitation to "at least one removable, replaceable transfer member," for example by removing "after use" A440-441. The "seal" limitation was amended to add structure for the seal, including that it has a first end and a second end with distinct elements. Slip Op. at 12.

B. District court decision

The district court granted summary judgment of noninfringement because it found no triable issue as to whether the accused device had a “removable, replaceable transfer member” literally or under the doctrine of equivalents. A33, A37-39. Millipore appealed the finding of noninfringement because a reasonable jury could conclude that the accused device literally had a “removable, replaceable transfer member,” or, in the alternative, had an equivalent of a “removable, replaceable transfer member.” Principal Br. at 40-52; Reply Br. at 7-16.

With respect to the “seal” limitation, the district court found no literal infringement, but did find a triable issue on equivalents. A26-33. The district court rejected the defendant’s prosecution history estoppel arguments, finding, based on the prosecution history,¹ that the “importance” of the seal amendment was “to ensure that the seals, as attached to the transfer member, would nonetheless allow for independent operation.” A29. “Otherwise ... the amendment *has no relevance* for purposes of evaluating equivalents as to internal components of the seal.” A29-30 (emphasis added). The district court further held that because the equivalents in question do not “prevent[] independent operation,” estoppel does not apply. A30, 33. The Panel left undecided Millipore’s appeal of

¹ To reach this conclusion, the district court quoted directly from Remarks in the Amendment in the prosecution: “none of the references show or disclose a seal formed like the present one, which is attached to the transfer member, thereby allowing independent operation of each holder between the inserted or withdrawn positions.” A29 (quoting from prosecution history Amendment at A2148).

the determination that there was no literal infringement as to the “seal” limitation. Principal Br. at 53-54; Reply Br. at 29-31.

C. Panel decision

With respect to literal infringement, the Panel held that the accused device does not literally have a “removable, replaceable transfer member” because “the transfer member does not exist when the device is disassembled.” Slip Op. at 8-9. Therefore, the Panel did not hold that the accused device literally lacked a transfer member, only that it literally lacked a transfer member that was *removable and replaceable*.

The Panel affirmed the district court’s noninfringement decision without reaching the district court’s doctrine of equivalents analysis. Instead, the Panel found that prosecution history estoppel bars Millipore’s arguments of infringement under the doctrine of equivalents. The Panel did not express disagreement with Millipore’s position that the amendment that resulted in the “removable, replaceable transfer member” language was broadening. Slip Op. 11-12. Rather, the Panel applied prosecution history estoppel to the “removable, replaceable transfer member” limitation based on the amendment to a different limitation, the “seal” limitation, that added “the requirement that the seal have a first and second end with distinct elements” for a reason related to patentability. Slip Op. at 12.

According to the Panel, “narrow[ing] the seal limitation ... *in turn* narrows the transfer member limitation,” triggering a *Festo* presumption, which, according

to the Panel, Millipore had “failed to rebut.” Slip Op. at 12 (emphasis added). As a result, according to the Panel, “[t]he district court should have concluded that Millipore was barred from arguing that the TAKEONE device infringes the transfer member limitation under the doctrine of equivalents.” Slip Op. at 12.

III. ARGUMENT IN SUPPORT OF PANEL REHEARING

Millipore seeks Panel rehearing because the Panel misapprehended facts and issues of law.

A. The Panel’s decision is contrary to longstanding precedent that amendment-based estoppel is determined with reference to amendment of the limitation at issue

The Panel’s decision that Millipore was barred from arguing that the device has an equivalent of the transfer member found not to be literally removable and replaceable is contrary to longstanding precedent that amendment-based estoppel is determined with reference to amendment of the limitation at issue. The limitation at issue, “removable, replaceable transfer member,” was not narrowed. The Panel improperly decided that an amendment to the “seal” limitation in turn narrows the “removable, replaceable transfer member” limitation, resulting in a presumption of estoppel.

It is improper to determine that narrowing one limitation causes a presumption of estoppel as to a different limitation because prosecution history estoppel is a limitation by limitation inquiry. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997) (where the patent holder fails to explain

the reason for an amendment to an element, “prosecution history estoppel would bar the application of the doctrine [of] equivalents *as to that element*”) (emphasis added); *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1103 (Fed. Cir. 2002) (estoppel can apply only if “*limitations at issue* were amended during prosecution”) (emphasis added).

B. The Panel’s conclusion that narrowing one limitation can “in turn” trigger a *Festo* presumption as to another limitation has been rejected by this Court en banc and in a precedential opinion

In the year that followed this Court’s en banc *Festo* decision that applied the Supreme Court’s *Festo* decision rejecting the absolute bar, this Court provided guidance in en banc and precedential decisions, on applying estoppel without an absolute bar, including that estoppel is to be applied on a limitation by limitation basis. *See Honeywell Int’l v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1144 (Fed. Cir. 2004) (en banc) and *Ericsson v. Harris*, 352 F.3d 1369, 1375 (Fed. Cir. 2003).

Sitting en banc in *Honeywell*, and citing *Festo* en banc 344 F.3d at 1367, this Court made clear that “[t]he scope of the patentee’s concession² is determined on a *limitation-by-limitation* basis” and went on to determine “[i]t necessarily follows that the presumption of surrender applies only to the amended or newly added

² Like the claims asserted in *Honeywell*, Claim 1 in the present action resulted from an amendment of a dependent claim into independent form and the cancellation of the independent claim.

limitation; there is no surrender of territory as to unamended limitations that were present in the original claim.” 370 F.3d at 1144 (en banc).

In *Ericsson*, a precedential decision, this Court rejected precisely the sort of analysis relied upon by the Panel in the present case. In that case, the following amendment was at issue:

1. . . . which, by the control signals ~~effectively disconnects~~ disables the speech signals amplifiers and ~~actively connects~~ enables the auxiliary amplifiers so that the speech signal amplifiers, which require power, only supply power to the telephone set when the receiver is off its cradle and a call can be made.

Even though “effectively disconnects *the speech signals amplifiers*” was amended to “disables *the speech signals amplifiers*” and “actively connects” was amended to “enables,” this Court did not apply estoppel as to “*the speech signal amplifiers ... only supply power to the telephone set,*” finding “[t]hat limitation was never amended and therefore cannot be subject to the *Festo* presumption.” 352 F.3d at 1375. This Court reasoned that the “only equivalence issue thus concerns when the speech signal amplifiers supply power, not whether they are ‘enabled’ or ‘disabled’ as opposed to ‘actively connected’ or ‘effectively disconnected,’ which was the subject of the amendment.” 352 F.3d at 1375 (emphasis in original).

Similarly, in the present case, the only equivalence issue concerns removability and replaceability of the transfer member, not the structure of the seal, which was the subject of the amendment.

C. Even if narrowing one limitation could in turn trigger a *Festo* presumption as to another limitation, estoppel prevents only the recapture of surrendered ground between the original claim limitation and the amended claim limitation

After erroneously relying on a narrowing amendment to the “seal” limitation to trigger the *Festo* presumption “in turn” in the “removable, replaceable transfer member” limitation, the Panel further erred by requiring rebuttal of the presumption without first determining whether the equivalent was within the surrendered ground resulting from the amendment to the seal limitation. Because the equivalent is not within the surrendered ground, rebuttal is not necessary.

The *Festo* presumption, even properly assessed, prevents at most recapture of territory ***surrendered*** by amendment. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738, 740 (2002) (considering what equivalents were surrendered and rejecting a “complete bar”); *Festo*, 344 F.3d at 1367 (“*Festo* [S.Ct.] imposes the presumption that the patentee has surrendered all territory ***between the original claim limitation and the amended claim limitation.***”) (emphasis added). Because Millipore’s amendment was the addition of structure to the seal limitation, Millipore did not surrender any subject matter relating to the transfer member’s removability and replaceability, which is what was found not to be literally satisfied by the accused device. Accordingly, Millipore need not rebut the *Festo* presumption to argue that the accused device has the equivalent of a transfer member that is removable and replaceable.

D. Even if narrowing one limitation could in turn trigger a *Festo* presumption as to another limitation, Millipore *did* rebut the presumption, as the district court found, and the Panel’s contrary finding is a material error of law and fact

Assuming *arguendo* that this Court is going to overrule prior precedent in spite of the arguments hereinabove, the Panel’s decision that Millipore did not rebut the presumption as to the “seal” limitation³ is contrary to fact. According to findings of the district court, that presumption is rebutted because the equivalent in question is tangential to the reason for the amendment:

For purposes of patentability, then, ***the importance of incorporating limitations on the elements of the seal*** from Claim 3 into Claim 1 was to ensure that the seal, as attached to the transfer member, would nevertheless ***allow for independent operation***. In other words, the amendment prevents Millipore from claiming devices with a seal, attached to a transfer member, that does not allow for independent operation of each holder. ***Otherwise, however, the amendment has no relevance*** for purposes of evaluating possible equivalents to the internal components of the seal described in the plain claim language... .

A29-30 (emphasis added). Therefore, the Panel’s decision rests on a material error of law and fact.

The Panel’s incorrect conclusion as to rebuttal of the presumption is based solely on a misapprehension that counsel’s response during oral argument that Millipore did not rebut the *Festo* presumption was directed to the “seal” limitation. Slip Op. at 12. To the contrary, counsel’s response was directed solely to the

³ The Panel stated, “Millipore chose not to present any argument on the issue to the district court.” Slip Op. at 12.

“removable, replaceable transfer member” limitation, which was the subject of the colloquy:

The Court: [I]t seems to me that this is a very strong case of prosecution history estoppel given the amendments to the claim. Do you want to respond to that briefly?

Ms. Glovsky: Is that with respect to the removable replaceable transfer ...

The Court: Yes.

Ms. Glovsky: ...member, Your Honor?

See Oral Arg. 16:40-16:53.

There was then an extended discussion regarding, *inter alia*, Millipore’s position that the accused device literally had a “removable, replaceable transfer member.” The Court then further asked:

The Court: ... [J]ust so I understand the record, as I understand your argument below in response to the prosecution history argument that was made by your friend on the other side was that the amendment was not narrowing ...

Ms. Glovsky: Correct, Your Honor.

The Court: ... was not limiting. But you never argued in the alternative that if in fact there was a conclusion by the trial court that the amendment was narrowing or limiting that you could rebut the presumption that would arise under *Festo*, is that right?

Ms. Glovsky: That’s correct, Your Honor, and I don’t think that would be necessary because it wasn’t a narrowing amendment.

See Oral Arg. 23:50-24:20. Counsel’s response was provided with the understanding that the amendment that was the subject of the question was to the “removable, replaceable transfer member” limitation, and not to the “seal” limitation.

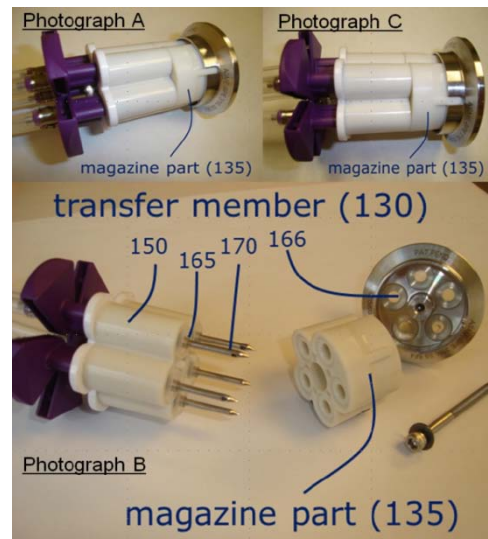
The district court held—quoting the prosecution history—that the “importance” of the seal amendment was “to allow for independent operation,” and “[o]therwise ... the amendment *has no relevance* for purposes of evaluating equivalents as to internal components of the seal... .” This is essentially a decision that it was tangential. A29-30 (emphasis added). The district court further held that because the equivalents in question do not “prevent[] independent operation,” estoppel does not apply. A30, 33. Because the district court found that there was no estoppel with respect to the seal limitation, similarly there should be no estoppel found as to the “removable, replaceable transfer member” limitation that was not itself narrowed. That is, even if it is found that the amendment to the “seal” limitation triggered a *Festo* presumption in the “removable, replaceable transfer member” limitation, the presumption was rebutted for the very reason that the district court found that the *Festo* presumption was rebutted for the “seal” limitation.

E. Because estoppel should not apply, Millipore renews its appeal of the district court’s equivalents decision

Millipore seeks rehearing and requests that the Panel decide that there is no estoppel and that a reasonable jury could find that a transfer member in the accused device is the equivalent of the claimed “removable, replaceable transfer member.” On this basis, Millipore seeks rehearing and reversal of summary judgment.

F. The Panel decision affirming a finding of no literal infringement with respect to the “removable, replaceable transfer member” limitation is based on a material error of fact resulting from a misstatement of counsel’s colloquy with the district court

More fundamentally, the Panel erred in finding that there was no genuine issue of material fact as to whether the accused device’s transfer member is removable and replaceable. *See* Slip Op. at 9. In Photographs A, B, and C reproduced here, Photograph A shows the accused device, Photograph B shows the accused device with “at least one removable, replaceable transfer member” 130 (holder 150, seal 165/166, and needle 170) removed from the magazine part 135, and Photograph C shows the “at least one removable, replaceable transfer member” replaced in the magazine part 135. Principal Br. at 14, 21.



The Panel found that “since the device lacks a seal when it is disassembled, it necessarily lacks the claimed ‘removable, replaceable transfer member.’” Slip Op. at 9. This finding is plainly incorrect. Seal components 165/166 are removable from the magazine part 135, as shown in Photograph B. They do not cease to exist upon removal. Further, seal 165/166 need not perform a sealing function when removed from the magazine part. The seal of Claim 1 is “for sealing [the] aperture” and once the device disclosed in the patent is removed from

the aperture the seal cannot seal the aperture. Similarly, the transfer member of Claim 1 can no longer transfer once the device is removed from the container. Because the transfer member disclosed and claimed in the patent no longer performs these functions, it is improper to expect more of a device accused of infringing Claim 1.

AllPure's argument, cited by the Panel, regarding a supposed "admission" by Millipore is contrary to the record and cannot support the Panel's finding. Contrary to the impression created by AllPure, Millipore's colloquy with the district court was that the *claimed* transfer member need not *function* as a transfer member when removed. A2518-19. There was, quite simply, no admission that the accused device lacked a removable, replaceable transfer member.

IV. ARGUMENT IN SUPPORT OF REHEARING EN BANC

In the absence of Panel rehearing, rehearing en banc is warranted because the Panel's decision is contrary to well-settled law that prosecution history estoppel is determined on a limitation by limitation basis. *See Warner-Jenkinson*, 520 U.S. at 33; *Festo*, 344 F.3d at 1367 (en banc); *Honeywell*, 370 F.3d at 1144 (en banc); *Abbott Labs.*, 287 F.3d at 1103; *Ericsson*, 352 F.3d at 1374-75. Left intact, the Panel's decision would lead to the result the Supreme Court has cautioned against because it would "disrupt the settled expectations of the inventing community" (*Festo*, 535 U.S. at 739 citing *Warner-Jenkinson*, 520 U.S. at 28) and "destroy[] the legitimate expectations of inventors in their property ... disrupt[] the

expectations of countless existing patent holders [and] subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by [the Federal Circuit's] decision.” *Festo*, 535 U.S. at 739 (internal quotations omitted). The Panel should correct this error on rehearing.

CONCLUSION

The Court should grant Panel rehearing or rehearing en banc. The Panel's prosecution history estoppel holding should be vacated and the Panel should address, and reverse, the district court's determination of summary judgment of noninfringement because a reasonable jury could find that the accused device has a “removable, replaceable transfer member,” at least under the doctrine of equivalents, if not literally.

Respectfully submitted,

/s/ Susan G. L. Glovsky

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ADDENDUM

United States Court of Appeals for the Federal Circuit

EMD MILLIPORE CORPORATION
(formerly known as Millipore Corporation),
MERCK CHEMICALS AND LIFE SCIENCE AB
(formerly known as Millipore AB),
AND MILLIPORE SAS,
Plaintiffs-Appellants,

v.

ALLPURE TECHNOLOGIES, INC.
(now known as AllPure Technologies LLC),
Defendant-Appellee.

2014-1140

Appeal from the United States District Court for the
District of Massachusetts in No. 1:11-CV-10221, Judge
Douglas P. Woodlock.

Decided: September 29, 2014

SUSAN G. L. GLOVSKY, Hamilton, Brook, Smith &
Reynolds, P.C., of Boston, Massachusetts, argued for
plaintiffs-appellants. With her on the brief was
LAWRENCE P. COGSWELL, III.

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INC.

CRAIG R. SMITH, Lando & Anastasi, LLP, of Cambridge, Massachusetts, argued for defendant-appellee. Of counsel was ERIC P. CARNEVALE.

Before PROST, *Chief Judge*, O'MALLEY and HUGHES,
Circuit Judges.

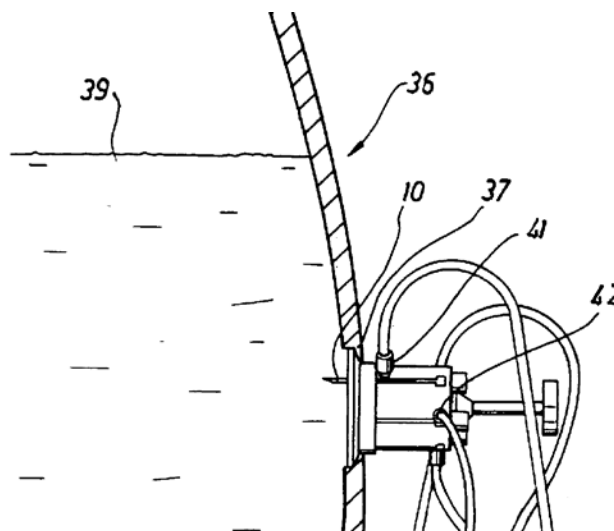
PROST, *Chief Judge*.

Plaintiffs-Appellants EMD Millipore Corporation, formerly known as Millipore Corporation; Merck Chemicals and Life Science AB, formerly known as Millipore AB; and Millipore SAS (collectively, “Millipore”) appeal the grant of summary judgment that Defendant-Appellee AllPure Technologies, Inc., now known as AllPure Technologies LLC, (“AllPure”) does not infringe the asserted claims of U.S. Patent No. 6,032,543 (“’543 patent”). *See EMD Millipore Corp. v. AllPure Techs., Inc.*, No. 11-10221, 2013 WL 5299372 (D. Mass. Sept. 17, 2013) (“*Summary Judgment Order*”). The district court found that AllPure’s TAKEONE device neither literally contains the claimed “removable, replaceable transfer member,” nor does it provide an infringing equivalent. *Id.* at *9. We agree with the district court that the TAKEONE device does not literally infringe. We also conclude that prosecution history estoppel prevents Millipore from asserting the doctrine of equivalents as to this claim limitation. On these grounds, we affirm the district court’s grant of summary judgment.

I. BACKGROUND

Millipore owns the rights to the ’543 patent, which discloses a device for introducing or withdrawing a sample from a container holding a fluid without contaminating the fluid. *See* ’543 patent abstract, col. 2 ll. 20-24. As Figure 5 depicts, the claimed device is attached to the side of a container holding a fluid medium. *Id.* at col. 1 ll. 54-56.

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INC.



'543 patent, Fig. 5

To avoid contamination problems, the '543 patent uses individual transfer members to maintain a closed system. '543 patent col. 5 ll. 20-23, col. 5 ll. 35-39, col. 6 ll. 23-26. Each transfer member has a needle embedded in a plastic holder and a seal surrounding the needle which attaches to the holder. '543 patent col. 3 ll. 11-35.

The '543 patent contains 14 claims, including 1 independent claim. Independent claim 1 is reproduced below:

1. A device for one of introduction and withdrawal of a medium into a container having an aperture formed therein for receiving said device, said device comprising:

at least one *removable, replaceable transfer member* for transferring a medium into and out of the container, *said transfer member comprising a holder, a seal for sealing said aperture, a hypodermic needle having a tip, said needle supported within said holder in a longitudinal direction thereof, wherein the seal has a first end comprised of a bellows-shaped*

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INC.

part sealingly attached to said holder, and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part, said membrane portion for sealing said aperture of said container, wherein said bellows-shaped part surrounds said needle and is deformable in a longitudinal direction, said membrane portion pierceable by the tip of the needle to form a sealable channel;

a fastening device for sealingly securing the transfer member via the seal with the aperture of the container, thereby forming a closed system, said fastening device comprising a flanged part sealingly secured in the aperture and formed with at least one hole therethrough in communication with an interior of said container, a magazine part for removable securement of said at least one transfer member, and a fastening and centering means for removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole.

'543 patent, claim 1 (emphases added).

AllPure's accused TAKEONE device is an aseptic sampling system that may be attached to the outside of a container holding a fluid medium and has cannulas that can be inserted into the container to withdraw a sample. The device is delivered fully assembled and sterilized, and it is intended to be disposed of following use. The TAKEONE device, in a disassembled state, is shown

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below. *Summary Judgment Order* at *7. The TAKEONE device's transfer member (130) is composed of a holder (150), a seal (comprising a bellows-shaped part (165) and a membrane (166)), and needles (170). *Id.* When disassembled, all components of the TAKEONE device's transfer member can be removed from the magazine part (135). *Id.*



The district court granted AllPure's motion for summary judgment of no infringement of the '543 patent, finding that "the TAKEONE device lacks a 'removable, replaceable transfer member' as claimed in the '543 patent." *Summary Judgment Order* at *7-8. The district court rejected Millipore's argument that a disassembled TAKEONE device satisfies this claim limitation. *Id.* at *8. The district court also found that the TAKEONE device does not provide an infringing equivalent of the limitation. *Id.*¹ We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

¹ In addition, the district court found that the TAKEONE device did not literally possess a seal with a "self-sealing membrane portion interiorly formed at an end of a bellows-shaped part," but it declined to grant

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III. STANDARDS OF REVIEW

Summary judgment is appropriate when there is “no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). While we review summary judgment decisions de novo, *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378 (Fed. Cir. 2008), “[i]nfringement, whether literal or under the doctrine of equivalents, is a question of fact.” *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). However, “a court may determine infringement on summary judgment ‘when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device.’” *Innovention Toys, LLC v. MGA Entmn’t, Inc.*, 637 F.3d 1314, 1319 (Fed. Cir. 2011) (quoting *Bai*, 160 F.3d at 1353).

Whether prosecution history estoppel applies to a particular argument, and thus whether the doctrine of equivalents is available for a particular claim limitation, is a question of law reviewed de novo. *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1290-91 (Fed. Cir. 2010).

IV. DISCUSSION

This appeal concerns Millipore’s challenges to the district court’s grant of summary judgment of no infringement. The district court found that AllPure’s TAKEONE

summary judgment of no infringement on this limitation under the doctrine of equivalents. *Summary Judgment Order* at *5-6. The district court also declined to grant summary judgment based on AllPure’s argument that Millipore is judicially estopped from taking the position that the TAKEONE device infringes the ’543 patent due to statements it made during prosecution of another patent. *Id.* at *3-4. However, we need not address these findings to resolve this appeal.

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device lacked the claimed “at least one removable, replaceable transfer member” both literally and under the doctrine of equivalents. For the reasons discussed herein, we conclude that there is no genuine issue of material fact relating to whether the TAKEONE device literally contains “at least one removable, replaceable transfer member.” We also conclude that the district court should have barred Millipore from asserting that the TAKEONE device contains an equivalent transfer member due to prosecution history estoppel.

A. No Literal Infringement

The district court construed the claim limitation “at least one removable, replaceable transfer member” to mean “at least one transfer member that can be removed from the magazine part of the device and replaced with at least one removable, replaceable transfer member.” See *EMD Millipore Corp. v. AllPure Techs., Inc.*, No. 11-10221, 2012 WL 4862772, at *5 (D. Mass. Oct. 11, 2012) (“*Claim Construction Order*”). Neither party has challenged this construction. However, the parties disagree over the meaning of the term “removed,” as contained in the district court’s construction. The district court explained that “remove” means “to move . . . by taking away or off” or to “put aside, apart, or elsewhere.” *Summary Judgment Order* at *7 (citing *Webster’s New International Dictionary* 1921 (3d. ed 1986)). The district court also noted that “[t]ake off” and “put apart” are significantly different from “take apart” or disassemble; “the former implies movement or separation of something as a whole, whereas the latter implies deconstruction.” *Id.*

In examining the TAKEONE device, the district court found that the transfer member lacked the necessary seal once it is removed. *Id.* at *8. “Upon separating the holder [150] from the various other elements, there ceases to be a seal, . . . with two ends comprising a bellows and a membrane, respectively. What Millipore characterizes as

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removal of a transfer member from the magazine part is, in fact, disassembly of a transfer member as defined in the '543 patent.” *Id.*

On appeal, Millipore challenges the district court’s interpretation of its own claim construction. It argues that summary judgment was inappropriate because there remains a genuine issue of material fact relating to whether disassembly of the transfer member could qualify as the claimed removal of the transfer member. Millipore claims that when the TAKEONE device is *disassembled*, all components of the transfer member are still *removed* from the magazine part (135), even if the components of the seal (i.e., the bellows-shaped part (165) and the membrane (166)) are no longer physically connected.

AllPure responds by arguing that there is no triable issue of fact—the TAKEONE device lacks a removable and replaceable transfer member. Claim 1 requires that at least one transfer member have a seal and be “removable, replaceable.” But in order for it to be removable and replaceable, the TAKEONE device must be disassembled. When it is disassembled, no seal exists because the required components are no longer connected. One part of the seal, the bellows-shaped part (165), remains attached to the holder (150), while the second part, the membrane (166), is separated from the rest of the transfer member. AllPure notes that Millipore’s counsel even admitted this fact, choosing instead to argue that a transfer member “does not have to still be a transfer member once removed.” J.A. 2519. However, according to AllPure, if the transfer member does not exist when it is removed, then the TAKEONE device does not have the claimed “at least one removable, replaceable transfer member,” so it cannot infringe.

We agree with AllPure and the district court. If a transfer member does not exist when the device is disassembled, as even Millipore’s counsel admitted, then there

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is no genuine issue of material fact over whether the TAKEONE device contains a “removable, replaceable transfer member” as is literally required by claim 1 of the ’543 patent. As the district court properly noted, “[t]he problem with Millipore’s characterization of ‘removal’ of a transfer member . . . is the absence of necessary component parts of the transfer member once it is removed [T]he part of the device removable from the magazine part must have all of the component parts—a holder, needle, and seal.” *Summary Judgment Order* at *7. Since the TAKEONE device lacks a seal when it is disassembled, it necessarily lacks the claimed “removable, replaceable transfer member.”

B. Prosecution History Estoppel Bars Millipore’s Doctrine of Equivalents Arguments

We next examine whether the district court erred in granting summary judgment of no infringement under the doctrine of equivalents. Even without literal infringement of a certain claim limitation, a patentee may establish infringement under the doctrine of equivalents if an element of the accused device “performs substantially the same function in substantially the same way to obtain the same result as the claim limitation.” *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (citation omitted) (quotation marks omitted). The district court concluded that it was not “possible for Millipore to maintain a claim for infringement under the doctrine of equivalents because the purportedly removable transfer member(s) of the TAKEONE device do not serve the same function or function in the same way as those in the ’543 patent.”² *Summary Judgment Order* at *8.

² As previously stated, the proper inquiry is actually whether the accused device performs *substantially* the

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As a preliminary matter, AllPure argues that the district court should not have considered whether Millipore could maintain a claim for infringement under the doctrine of equivalents because prosecution history estoppel bars such a claim. Prosecution history estoppel applies when an applicant during patent prosecution narrows a claim “to avoid the prior art, or otherwise to address a specific concern . . . that arguably would have rendered the claimed subject matter unpatentable.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 30-31 (1997). Estoppel then bars the applicant from later invoking the doctrine of equivalents to recapture the surrendered ground. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002).

There is a presumption that prosecution history estoppel applies when a patentee has filed an amendment seeking to narrow the scope of a claim, and “the reason for that amendment was a substantial one relating to patentability.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003) (en banc). The patentee bears the burden of rebutting the application of prosecution history estoppel by establishing one of three exceptions: (1) the equivalent was unforeseeable at the time of the application; (2) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or (3) there is some other reason suggesting that the patentee could not

same function in *substantially* the same way to obtain the same result. *Aqua Tex Indus.*, 419 F.3d at 1382. Millipore argues that the district court used the wrong standard, but for the reasons discussed herein, we conclude it was unnecessary for the district court to even undertake a doctrine of equivalents analysis. Therefore, this issue is moot.

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reasonably be expected to have described the equivalent.
Festo Corp., 535 U.S. at 740-41.

During prosecution of the '543 patent, the applicant amended claim 1's language, adding, inter alia, the requirement that the transfer member's seal have "a first end comprised of a bellows-shaped part sealingly attached to said holder, and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part." J.A. 2143. The applicant stated that the purpose of the amendment was to make claim 1 "allowable and distinguishable over the cited references." J.A. 2148. The district court found that although claim 1 "was narrowed to allow the device to be patented over prior art, it was not narrowed so as to disclaim all multi-part seals." *Summary Judgment Order* at *5. The district court then considered Millipore's doctrine of equivalents arguments on the merits.³ *Id.* at *8.

Millipore argues that the claim language was actually broadened. Prior to amendment, claim 1 required "at least one transfer member . . . whereas the transfer member . . . is removable for replacement thereof *after use*." J.A. 341 (emphasis added). Because the amended claim 1 no longer contains the "after use" language, Millipore suggests that the claim is broader and, therefore, prosecution history estoppel cannot apply. *See* J.A. 440-41.

³ The district court discussed prosecution history estoppel in a separate portion of its summary judgment order. *See Summary Judgment Order* at *5. However, since there is only one seal in claim 1, the district court's statements about prosecution history estoppel and a multi-part seal pertain equally to the "at least one removable, replaceable transfer member" that is at issue.

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We disagree with Millipore and conclude that it was unnecessary for the district court to perform a doctrine of equivalents analysis because prosecution history estoppel bars Millipore's arguments. Although the applicant eliminated the "after use" language, the applicant nonetheless added the requirement that the seal have a first and second end with distinct elements. This narrows the seal limitation, which in turn narrows the transfer member limitation. And the applicant even stated in its reasons for amendment that "none of the references show or disclose *a seal formed like the present one.*" J.A. 2148 (emphasis added). Thus, these amendments were added to overcome a previous rejection. And to the extent this statement is ambiguous, we note that the Supreme Court has stated "[w]here no explanation is established . . . the court should presume that the patent applicant had a substantial reason related to patentability for including the limiting element added by amendment." *Warner-Jenkinson*, 520 U.S. at 33.

The district court should have proceeded under the presumption that prosecution history estoppel applies. Millipore then had the burden to rebut the presumption through one of the three enumerated exceptions, but Millipore chose not to present any argument on this issue to the district court. *See* Oral Arg. 24:06-24:20, *available at* <http://www.cafc.uscourts.gov/oral-argument-recordings/14-1140/all> ("Q: You never argued in the alternative that if in fact there was a conclusion by the trial court that the amendment was narrowing or limiting, that you could rebut the presumption that would arise under *Festo*? A: That is correct, your honor . . ."). Instead it argued that the amendment was not narrowing. *See* J.A. 2208-09. Since Millipore failed to rebut the presumption, the district court should have concluded that Millipore was barred from arguing that the TAKEONE device infringes the transfer member limitation under the doctrine of equivalents. This error, however, does not change the

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outcome of this case, as the district court still proceeded to grant summary judgment of no infringement under the doctrine of equivalents on the merits. *See Summary Judgment Order* at *8-9.

V. CONCLUSION

Since there is no genuine dispute of material fact regarding whether the TAKEONE device contains a “removable, replaceable transfer member,” either literally or under the doctrine of equivalents, we affirm the district court’s grant of summary judgment of no infringement.

AFFIRMED

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 29th day of October, 2014, I caused Plaintiffs-Appellants' Combined Petition for Panel Rehearing and Rehearing En Banc to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

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